

REMARKS

Reconsideration and allowance of the present application are respectfully requested. Claims 1-9 and 12-20 are pending in this application. Claim 1 is an independent claim. No new matter has been added.

Rejection under 35 U.S.C. § 103

Claims 1-7 and 10-20 stand rejected under 35 U.S.C. § 103(a) as being anticipated Sabol et al. (US 2004/0122719) "Sabol," in view of Urquhart et al. (US 2004/0073454) "Urquhart." This rejection is respectfully traversed.

Claim 1 recites, *inter alia*,

storing, by a test system, test criteria for the data, the test criteria correlated with the performance specification, the performance specification being one of specifications or instructions of a research project, standard operating procedures for medical procedures or treatments, inclusion and exclusion criteria for a clinical study, instructions to a patient or doctor, times or durations for physical activities and examination methods to be complied with.

At least this feature is not disclosed or suggested by Sabol and Urquhart, alone or in combination.

Sabol discloses a medical resource processing system. The system may provide material to a patient such as "structured video and/or audio recordings of questions and answers." Paragraph [0332] of Sabol. The material provided is for the patient. Resources that can be processed include reference sources which represent information about "medical events, medical conditions, disease state," and financial information. As recited in paragraph [0052] of Sabol,

The data resources do not, in general, require information to be gathered directly from the patient. Rather, these resources are more general in nature and may be obtained through data reference libraries, subscriptions, and so forth.

Thus, the data of Sabol represent general medical knowledge rather than a set of rules and performance specifications.

To maintain the validity and quality of such data, the validation and data management module 324 may carry out specific functions, typically bi-directionally, as indicated in FIG. 22. Such functions may include those of the reconciliation modules as indicated at reference numeral 326, which can reconcile or validate certain data, such as based upon time of entry, source of the data, or any other validating criteria. Where such reconciliation or validation is not available, such as due to conflicting updates or inputs, such matters may be flagged to a user for reconciliation.

Paragraph [0352] of Sabol.

On page 3 of the Office Action, the Examiner relies on paragraphs [0004], [0008] and [0332] of Sabol to teach the “storing,” of claim 1. However, paragraphs [0004], [0008] and [0332] of Sabol do not disclose or suggest “test criteria ... correlated with the performance specification.” For example, paragraph [0332] of Sabol discloses “structured video and/or audio recordings of questions and answers,” not any criteria for implementing a test. Moreover, paragraph [0004] of Sabol recognizes various data acquisition techniques, but fails to recite storing “test criteria ... correlated with the performance specification.”

Consequently, Sabol fails to disclose or suggest the “storing, by a test system, test criteria for the data, the test criteria correlated with the performance specification,” as set forth in claim 1.

Moreover, claim 1 has been amended to clarify the “test data ... correlated with the performance specification,” by amending claim 1 to recite

the performance specification being one of specifications or instructions of a research project, standard operating procedures for medical procedures or treatments, inclusion and exclusion criteria for a clinical study, instructions to a patient or doctor, times or durations for physical activities and examination methods to be complied with

Sabol fails to disclose or suggest any test criteria correlated with the above possible performance specifications.

Urquhart discloses monitoring patient compliance with a prescribed drug regime. Monitoring devices are attached to drug dispensers and data about time and amount of drugs taken from the dispenser by a patient are collected. The data are subsequently transmitted to a server, where they are stored for analysis and later accessed by a physician. *See, e.g.*, paragraph [0014] of Urquhart.

However, neither Sabol nor Urquhart teaches that the test criteria (i.e., the comparison between the recorded and prescribed dosage) are stored in a test system. According to Urquhart, said criteria are rather an intrinsic property of a processing device used for data analysis. For example, paragraph [0040] of Urquhart provides:

PC 16 operates as a communication link to one or more remote stations. One such remote station is a PC 18 provided at a physician location. Another such remote station is a server 20, such as a webserver hosting the portal website designed to provide the analysis services discussed above. In particular, server 20 operates as a processing device which analyzes the received dosing history data and any information provided to the system by the physician and thereby generates analysis data used for a patient, including dosage histories, analysis of expected results of dosage history, treatment advice, and recommendations.

Consequently, one of ordinary skill in the art would hard-code the analysis criteria. As such, the analysis criteria are not stored by a test system. Moreover, the criteria of Urquhart are not “test criteria” for any of the performance specifications identified in claim 1. Therefore, Urquhart fails to disclose or suggest the “storing, by a test system, test criteria for the data, correlated with the performance specification,” as set forth in claim 1.

Since both Sabol and Urquhart fail to disclose or suggest the “storing,” of claim 1, Sabol and Urquhart, alone or in combination fail to render claim 1 obvious.

Claims 2-7 and 12-20 are patentable at least by virtue of their dependency on claim 1.

Claims 8-9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sabol in view of Urquhart and further in view of Miller et al. (US 5,446,653) "Miller." This rejection is respectfully traversed.

The Examiner correctly acknowledges that the features of claims 8-9 are not disclosed or suggested by Sabol and Urquhart. However, the Examiner alleges that these features are taught by Miller. Even if Miller taught the features of claims 8-9 (which Applicants do not admit) and that Miller could be properly combined with Sabol and Urquhart (which Applicants do not admit), Miller fails to cure the deficiencies of Sabol and Urquhart as described above with reference to claim 1. Therefore, Sabol, Urquhart and Miller fail to render claims 8-9 obvious.

For at least the foregoing reasons, Applicants respectfully request that the Examiner withdraw the rejections under 35 U.S.C. § 103.

CONCLUSION

Accordingly, in view of the above remarks, reconsideration of the objections and rejections and allowance of each of claims 1-9 and 12-20 in connection with the present application is earnestly solicited.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Donald J. Daley at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. §1.17; particularly, extension of time fees.

Respectfully submitted,

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